

Notice of Allowability	Application No.	Applicant(s)	
	10/591,097	RODRIGUEZ ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 4/9/10.
2. ☒ The allowed claim(s) is/are 1, 2, and 7-10.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
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| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>6/24/10</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Adam Warwick Bell on June 24, 2010.

The application has been amended as follows:

Claims 1, 2, 7, 8 and 10 have been amended as follows:

1. A method for identifying a test compound that has the property of suppressing chemically-induced carcinogenesis in mammalian cells, the method comprising: a) providing RWPE-1 and RWPE-2 cells, b) measuring expression of a set of genes in the RWPE-1 and the RWPE-2 cells wherein the set of genes comprises at least the genes: ADAM9, BUB1B, CD46, GJA1, HIF1A, ITGB1, LAMB1, MAD2L1, the gene encoding FLJ20372, Formin binding protein 3, PSMC6, RANBP2, CSPG6, SP3, THBS1, TTK, PRKAR1A, TOB1, and Acidic leucine-rich nuclear phosphoprotein 32 family, member E, c) exposing RWPE-1 and RWPE-2 cells to the test compound, d) re-measuring the expression of the [named] genes by the cells after exposure to the test compound, and e) comparing the expression of the [named] genes in RWPE-1 cells with the expression of the [named] genes in RWPE-2 cells, [f)] wherein a coordinated increase in expression of at least two-fold of all of the above genes in RWPE-1 cells but not in RWPE-2 cells following exposure to the test compound indicates that the test compound has the

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property of suppressing chemically-induced [foci formation] carcinogenesis in mammalian cells.

2. The method of claim 1 wherein the degree of increase of expression of the [plurality of] genes is measured using a weighted average.

7. The method of claim 1 wherein the [plurality] set of genes further comprises at least one of the genes selected from the group consisting of [PKA, TOB1, ERBIN, NIP3, TSP1, BUB1B, TTK, PSMC6,] ERBB2IP, BNIP3 and USP1.

8. The method of claim 1 wherein the [plurality] set of genes comprises genes selected from the group consisting of: genes that regulate apoptosis, genes involved in suppression of cell proliferation, mitotic check point genes, genes involved in protein degradation, and genes that up-regulate the gap junction proteins.

10. The method of claim 9 wherein the array comprises a plurality of polynucleotide probes that are specifically complementary to [a plurality of genes named in Claim 1 as shown in Table 1] said genes.

Claims 3, 13, 14, 19-22 and 27 have been cancelled.

The title has been amended to read:

--Methods for Identifying Compounds that Suppress Chemically-Induced Carcinogenesis--.

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The following is an examiner's statement of reasons for allowance:

A. The previous objection to claims 1-3 and 8-11, the rejection of claims 1-3 and 8-11 under 35 USC 112, second paragraph, the rejection of claims 1-3 and 8-11 under 25 USC 112 first paragraph (enablement), and the rejection of the claims under 35 USC 102 as being anticipated by Li et al have been obviated by the amendments to the claims.

B. In view of the allowability of claims 1, 2 and 8-10, the subject matter of claim 7 has been rejoined with the elected invention and fully examined for patentability under 37 CFR 1.104.

The restriction requirement as set forth in the Office action mailed on April 17, 2009, as it pertained to the requirement to elect a particular combination of genes is hereby withdrawn. That is, the elected subcombination of genes recited in claim 1 has been rejoined with the additional genes recited in claim 7. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

C. It is noted that claim 7 has been amended to recite the particular gene symbols listed in Table 1 of the specification and in particular, ERBIN has been amended to read

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"ERBB2IP," and NIP3 has been amended to read "BNIP3."

D. The closest prior art of Li et al (page 1012) discloses methods comprising providing PC3 human prostate cancer cells, measuring expression by the cell of each of the 22,215 genes which hybridize to the probes present in the Affymetrix U133 Array, exposing the cells to the compounds indole-3-carbinol (IC3) and 3,3'-dinodolylmethane (DIM), and determining the expression of each of the 22,215 genes which hybridize to the probes present in the Affymetrix U133 array. The Affymetrix U133 array comprises each of the presently claimed genes ADAM9, BUB1B, CD46, GJA1, HIF1A, ITGB1, LAMB 1, MAD2L1, the gene encoding FLJ20372, Formin binding protein 3, PSMC6, RANBP2, CSPG6, SP3, THBS 1, TTK, PRKAR1A, TOB 1, and Acidic leucine-rich nuclear phosphoprotein 32 family, member E, as evidenced by the present specification (page 13, para [40]). However, Li et al does not teach or suggest the presently claimed method of identifying a test compound that has the property of suppressing chemically-induced carcinogenesis in a mammalian cell comprising measuring the expression of the ADAM9, BUB1B, CD46, GJA1, HIF1A, ITGB1, LAMB 1, MAD2L1, the gene encoding FLJ20372, Formin binding protein 3, PSMC6, RANBP2, CSPG6, SP3, THBS 1, TTK, PRKAR1A, TOB 1, and Acidic leucine-rich nuclear phosphoprotein 32 family, member E genes in RWPE-1 and RWPE-2 cells prior to and following exposure to a test compound, and comparing the expression of the genes in the RWPE-1 and RWPE-2 cells, wherein a coordinated an increase of at least two-fold of each of said genes in RWPE-1 cells but not in RWPE-2 cells following exposure to the test compound

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indicates that the test compound has the property of suppressing chemically-induced carcinogenesis in mammalian cells.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634